Remarks

Claims 1, 3-6, 16, and 17 were rejected under 35 U.S.C. §112 for indefiniteness as being substantial duplicates of claim 2. In support of the rejection, the Office Action stated, at page 4:

> In response, Applicant discloses in the instant specification and claims one crystalline form of a compound. Although the description of the one crystalline form in claims 1, 3-6, 16 and 17 is not as detailed as in claim 2, claims are all directed to a single crystalline form, i.e. Form V. Further, since no other ingredient is recited in the pharmaceutical composition of claim 16, the claim reads on just Form V. Therefore, claims 1, 3-6, 16 and 17 are directed to the same product as found in claim 2 and hence, are duplicates of claim 2.

The Applicants respectfully traverse this rejection. An applicant has the right to claim an invention in a reasonable number of ways. *See In re Chandler*, 319 F.2d 211, 225, 138 U.S.P.Q. 138, 148 (CCPA 1963): "[A]pplicants should be allowed reasonable latitude in stating their claims in regard to number and phraseology employed. The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged."

The Applicants right to claim the invention in a reasonable number of ways includes the right to use different terminology to define the exact same subject matter. See, e.g., *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F. 3d 1374, 1380, 77 U.S.P.Q. 2d 1988, 1993-1994 (Fed. Cir. 2006):

> Different claims with different words can, of course, define different subject matter within the ambit of the invention. On the other hand,

> claim drafters can also use different terms to define the exact same subject matter. Indeed this court has acknowledged that two claims with different terminology can define the exact same subject matter. [underscoring added]

The applicant's right to claim an invention in a reasonable number of ways is especially strong in the case of claims to crystalline forms since the characterization of crystalline forms requires complicated analyses by such techniques as PXRD, single crystal X-ray diffraction, infrared spectroscopy, and raman spectroscopy. Small, inevitable uncertainties in the measurements produced by these techniques require that the applicant be granted latitude in the choice of language in order for the applicant to have a fair opportunity to properly capture the invention in the claims.

Thus, even if claims 1-6, 16, and 17 were directed to exactly the same subject matter, i.e., had exactly the same scope, the Applicants should be permitted to maintain claims 1-6, 16, and 17 in the present application. This is especially so for claims 2-5 and 17 because claims 2-5 and 17 are independent claims. *See Curtiss-Wright,* 438 F. 3d at 1380-1381, 77 U.S.P.Q. 2d at 1994: "It is not unusual that separate claims may define the invention using different terminology, especially where (as here) independent claims are involved." (quoting *Hormone Research Found. v. Genentech, Inc.,* 904 F.2d 1558, 1567, n.15, 15 U.S.P.Q. 2d 1039, n.15 (Fed. Cir. 1990).

An additional consideration argues that claims 1-6, 16, and 17 should not be rejected as substantial duplicates. M.P.E.P. §706.03(k) states that "mere difference in scope between claims has been held to be enough" to prevent claims from being considered substantial duplicates.

Each of pending claims 1, 3-6, 16, and 17 differs in scope from claim 2. In determining the scope of the claims, the Office Action is ignoring the plain language

of the claims and is looking beyond the claims to something outside the language of the claims ("[The] claims are all directed to a single crystalline form, i.e. Form V."). In reaching this conclusion about the scope of the claims, the Office Action ignores the different language used by the different claims ("Although the description of the one crystalline form in claims 1, 3-6, 16 and 17 is not as detailed as in claim 2 ...") and the different scopes thereby conferred on the claims by their use of different language. This is improper. It is settled law that the language of the claims determines the scope of the claims. See, .e.g., *Home Diagnostics, Inc. v. Lifescan, Inc.*, 381 F. 3d 1352, 1355, 72 U.S.P.Q. 2d 1276, 1278 (Fed. Cir. 2004) "[T]he claim language itself governs the meaning of the claim;" *Vitronics Corp. v. Conceptronic, Inc.,,* 90 F.3d at 1582, 39 U.S.P.Q. 2d 1573, 1576 (Fed. Cir. 1996): "[W]e look to the words of the claims themselves ... to define the scope of the patented invention."

Focusing on the words used in the claims leads to a conclusion that each of claims 1, 3-6, 16, and 17 differs in scope from claim 2. While all of the claims are directed to a particular crystalline form of atorvastatin, the scope of coverage of that crystalline form varies according to the language used in each claim. Claim 2 is directed to a crystalline form of atorvastatin that must have an X-ray powder diffractogram substantially as that of the diffractogram depicted in claim 2. In contrast, none of claims 1, 3-6, 16, and 17 use language referring to the diffractogram depicted in claim 2. Thus, none of these claims require that the crystalline forms claimed have a diffractogram substantially as depicted in claim 2. Furthermore, different proofs would be required for claim 2 and for each of claims 1, 3-6, 16, and 17 in order to determine if a particular crystalline form of atorvastatin falls within the scope of those claims. These considerations indicate that there is a difference in scope between claim 2 and each of claims 1, 3-6, 16, and 17.

Furthermore, all of the claims differ in scope because it is necessary to satisfy different limitations to fall within the scope of each claim. Claim 1 requires that the claimed crystalline form be prepared by a certain process. Claim 2 requires that the claimed crystalline form have a PXRD substantially as in the depicted diffractogram. Claim 3 requires three particular PXRD peaks, with one of the peaks having a maximum at a certain position. Claim 4 requires a certain ^{13}C NMR spectrum. Claim 5 requires specific NMR signals. Claim 6 requires a certain water content. Claim 16 is directed to a pharmaceutical composition comprising a therapeutic amount of the claimed crystalline form. Claim 17 requires a combination of PXRD peaks and NMR signals.

Moreover, the Office Action is incorrect in its view that an application may contain only one claim to a crystalline form. In *Ex parte Gring*, 158 U.S.P.Q. 109 (Pat. & Tr. Office Bd. App. 1967), claims 1 and 5 read as follows:

> 1. A novel boehmite alumina product with particles of irregular edges, a pore structure totalling at least about 0.5 cc. per gram in pores larger than 80(Å) in size, an average crystallite size greater than about 40(Å), up to about 200(Å) by X-ray diffraction and composed of a non-homogeneous integral aggregation of polycrystalline boehmite sub-units, said particles having a largest dimension of at least about 500(Å) by electron microscope.
>
> 5. The product of claim 1 which is that crystallographically depicted in Figure 1.
>
> 158 U.S.P.Q. at 110.

The Examiner had found that claim 5 was a substantial duplicate of claim 1. The Board of Appeals reversed this finding.

The holding of *Gring* is reinforced by the fact that the U.S. Patent & Trademark Office routinely grants patents containing more than one claim to a

particular polymorph. See, e.g., U.S. Patent No. 6,900,221; U.S. Patent No. 6,903,106; and U.S. Patent No. 7,148,231.

In view of the above, a rejection of claims 1, 3-6, 16, and 17 as being substantial duplicates of claim 2 is improper and it is requested that this rejection be withdrawn.

The time for responding to the Office Action was set for March 29, 2007. Enclosed is a Petition for the Extension of Time under 37 C.F.R. § 1.136(a) for a period sufficient to permit the filing of this response.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with this filing, or any defect seen to be remaining in this application after this filing. The Commissioner is authorized to charge Kenyon & Kenyon's Deposit Account No. 11-0600 for the Petition fee and any other fees required to effect this Conditional Petition.

Respectfully submitted,

By Joseph A Coppola

Dated: JUNE 29, 2007

Joseph A. Coppola
Reg. No. 38,413

KENYON & KENYON LLP
One Broadway
New York, NY 10004
(212) 425-7200 (telephone)
(212) 425-5288 (facsimile)
CUSTOMER NUMBER 26646